

### REMARKS

Claims 2-16 and 18-88 are pending. Claims 8-16 and 24-88 have been withdrawn from consideration.

Claims 2-7 and 18-23 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.K. Patent Application No. 2,225,321 to Cossement et al. (“*Cossement*”). Claims 6-7 and 22-23 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Claims 3, 7, 19, and 23 have been rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. Claims 2, 6, 18, and 22 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicants respectfully make reference to the recent decision of the Board of Patent Appeal and Interferences in *Ex Parte Buchi* (September 6, 2007), a copy of which is attached. Applicants respectfully assert that *Ex Parte Buchi* has direct bearing on the resolution of issues in the present patent application.

Applicants respectfully request reconsideration and allowance of all pending claims in view of the remarks set forth below.

#### I. ANTICIPATION REJECTION OVER COSSEMENT

The Examiner has rejected claims that recite polymorphic forms of levorotatory cetirizine dihydrochloride (Claim 19) and dextrorotatory cetirizine dihydrochloride (Claim 3) as allegedly anticipated by Examples set forth on pp. 8-10 of *Cossement*. The Examiner appears to suggest that the Examples of *Cossement* inherently anticipate the claimed polymorphic forms.

Applicants respectfully disagree.

To establish a *prima facie* case of inherent anticipation, the Examiner must show scientific rationale or objective evidence tending to show inherency. See MPEP §2112. See also *Ex parte Buchi*, Sl. Op., at p. 6. Only then the burden will

shift to the Applicants to disprove the inherency. See *Ex Parte Buchi*, Sl. Op., at page 7, citing, *Ex Parte Skinner*, 2 USPQ.2<sup>nd</sup> (BNA) 1788 (BPAI 1986). See also *Ex parte Havens*, Appeal No. 2001-0091, Sl. Op., at pp. 3-5, a copy of which is attached herewith.

In the present case, as in *Buchi* and *Havens*, the evidence adduced by the Examiner does not justify shifting of the burden. While *Cossement* may disclose a crystalline form, the rejected claims recite a particular polymorph. What are the grounds for the Examiner's belief that the polymorphs in *Cossement* are identical to the claimed polymorphs? As in *Buchi* and *Havens*, the Examiner did not provide a reason why the burden should shift to the applicants, and therefore did not set forth a *prima facie* case of inherency.

Second, to establish inherency, the reference's teachings or extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and it would be so recognized by persons of ordinary skill." See *In re Robertson*, 49 U.S.P.Q.2d (BNA) 1949, 1950-51 (Fed. Cir. 1999), cited in MPEP §2112. What would be the objective evidence of inherency in Examiner's view? Why would one skilled in the art recognize that the procedure in *Cossement*'s examples would necessarily result in the claimed polymorphs?

Withdrawal of the anticipation rejection over *Cossement* is respectfully requested.

## II. ENABLEMENT REJECTIONS

The Examiner has rejected Claims 6-7 and 22-23 for alleged lack of enablement.

Applicants respectfully disagree.

The bases for this rejection are not clear to the Applicants.

The test for enablement is well established. The issue is whether the disclosure, as filed, enables an artisan to make and use the claimed invention without undue experimentation. *See* MPEP §2164.01. In the present patent application, it is not clear how this test may be not satisfied.

For example, the rejected claim 6 recites a formulation containing a particular crystalline form of dextrorotatory cetirizine dihydrochloride in combination with one or more excipients. The methods of making of various qualifying formulations are extensively and clearly described throughout the specification of the present patent application. What requires experimentation that is undue? An artisan is clearly instructed to take the explicitly described polymorphic form and put it together with clearly described excipients in the described manner. Thus, the issue of undue experimentation should not even arise. *Cf. e.g., Ex Parte Buchi*, Sl. Op. at pages 3-4.

Withdrawal of the enablement rejection is respectfully requested.

### III. WRITTEN DESCRIPTION REJECTION

Claims 3, 7, 19, and 23 have been rejected for alleged failure to comply with the written description requirement. It appears the Examiner suggests that the written description requirement necessitates inclusion of the entire X-ray pattern in the claims.

Applicants respectfully disagree.

It is well established in the law that the applicant is allowed to be own lexicographer. The Applicants have chosen to define the invention as a crystalline form of the compound having at least certain number of recited peaks. The Examiner is respectfully requested to set forth any law that prevents a patent applicant from doing so.

Withdrawal of this rejection is respectfully requested.

#### IV. INDEFINITENESS REJECTIONS

Claims 2 and 18 have been rejected as allegedly indefinite for incorporating a figure by reference. According to the Examiner, Applicants should recite the peaks of the XRD pattern instead.

Applicants respectfully direct the Examiner's attention to the nature of the claimed subject matter. The rejected claims do not recite the polymorphic form *per se*. Rather, the claims recite the crystalline form having the particular X-ray pattern. Separate claims (Claims 3 and 19) cover the subject matter that the Examiner suggests as an alternative. Thus, Applicants are truly unable to claim this subject matter in different way, fully complying with the requirements of MPEP §2173.05.

Withdrawal of this rejection is respectfully requested.

Claims 6 and 22 have been rejected as allegedly indefinite for reciting "effective amount." According to the Examiner, "the term 'effective amount' is indefinite where the claim fails to state the function which is to be rendered effective."

Applicants respectfully disagree.

The term "effective amount" has been held definite when the supporting disclosure removes the uncertainty as to the function. *See* MPEP §2173.05(a). III. The proper test is "whether or not one skilled in the art could determine specific values . . . based on the disclosure." *See id.*, citing *In re Mattison*, 184 USPQ 484 (CCPA 1975) and *Ex parte Skuballa*, 12 USPQ2d 1570 (BPAI 1989). In other words, the current law is clear that the function of "effectiveness" does not need to be recited in the claim itself and may be set forth in the specification. In the

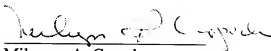
present case, the specification provides ample support for this term. *See, e.g.*, [0068]-[0070].

Withdrawal of this rejection is respectfully requested.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees due and owing in connection with this matter, please charge the same to our Deposit Account No. 50-3221.

Respectfully submitted,

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